

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

FEDERAL TRADE COMMISSION, Plaintiff, v. DIRECT MARKETING CONCEPTS, INC, et al, Defendants	CIVIL ACTION NO. 04-CV 11136GAO
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DECLARATION OF LARRY HAASE,
IN RESPONSE TO THE DECLARATION OF CHRISTINE SKIBOLA, PH.D.
REGARDING HER REVIEW OF SEA VEGG™
AND THE INFOMERCIAL BY ITV

I, Larry R. Haase, hereby declare as follows:

Introduction and Qualification

1. I am currently the President of 9 into1 Consultants, a consulting company whose clients primarily consist of start-up or emerging nutraceutical and alternative medical companies seeking management, sales, marketing, and product development advice. For the past 10 years I have consulted for many clients including companies developing liquid sea vegetable supplements, bone and joint supplements, liquid mineral supplements, and several anti-aging supplements
2. I have held executive positions in several companies. I was President of Hata Biotics, Inc., a company that developed and imported a new probiotic product from Japan. I was Business Unit Director of Nextech Healthcare, Inc. for five years. This company developed and marketed nutritional products and laboratory test kits. I was President of ACT, Inc., an emerging nutraceutical company that specialized in anti-aging products. Prior to these endeavors, I was Director of International Sales for RAI, a company that developed and marketed reagents and test kits to the clinical laboratory.

3. I am presently an advisor to Parkamins, Inc., a company that has developed a complete Parkinson treatment modality. I am also science advisor for BELD Global, a company that specializes in lymphatic drainage techniques.
4. I have published articles on pain and cholesterol testing in journals both in the US and in Europe.
5. An accurate and current resume is provided as an addendum to this Declaration.

Health Benefits of Seaweed

1. The literature is replete with articles describing the positive relationship between seaweed and various pathophysiologies, and seaweed's use as a dietary supplement is well established in the nutrition industry. It's acceptance as an important nutritional supplement is established and prevalent in many countries and cultures, including the United States.
2. As part of the review of Dr. Skibola's Declaration and comments, an Internet/PubMed search for health benefits of Seaweed was conducted. The search produced 230 articles supporting the health benefits of seaweed in various categories, including:
 - Anticoagulant Properties of Seaweeds: 86 articles
 - Antioxidant Properties of Seaweeds: 40articles
 - Anti-tumor Properties of Seaweeds: 27 articles
 - B₁₂ Supplementation Using Seaweeds:10 articles
 - Benefits of Seaweeds on Skin: 23 articles
 - Seaweeds to Treat Herpes:19 articlesOther related articles included:
 - Seaweeds to Normalize Thyroid Function (i.e., iodine content); and thus Weight Control
 - Seaweed to Treat Cerebrovascular Diseases Independent Of Hypertension

Review of the Infomercial

1. The infomercial was reviewed for health benefit statements that could not be substantiated, or health benefit statements that exceeded those allowed for dietary supplements (i.e. diagnosed, prevented, treated, mitigated, or cured disease).
2. This infomercial was presented in the format of an interview. The interviewer asked many leading questions regarding the health benefits of Sea Vegetation. Mr. Scott Kennedy, the spokesman for the Company and the product did not (or would not) specifically answer or address any of the direct disease-specific benefits questions posed by the interviewer. Rather, in general, it talked about the overall health benefits enjoyed by cultures that eat seaweed as part of their diet, or took seaweed supplements. Additionally, the screen often had the disclaimer tag as required by the 1994 Dietary Supplement Health and Education Act, as amended (DSHEA).
3. The only direct claim statement that Mr. Kennedy made with regard to Sea Vegg™ was in relation to weight loss. This issue is addressed below.

Review of the Declaration of Christine Skibola, Ph.D.

1. Dr. Skibola has reviewed the labeling and the infomercial of Sea Vegg™. I have reviewed her comments and, in general, can not agree with some of her stated observations, or with her conclusions.
2. Dr. Skibola contends in her review of the infomercial statements and label claims that the product is “manufactured from a combination of 12 different sea vegetables” and that this statement cannot be confirmed. The Company confirmed that this statement is true, and that twelve different species of seaweed are included in the product. The specific names of the twelve species are not listed on the label because the product is manufactured from a pool of fifteen different sea vegetables, depending on which ones are in season at the time of production. Therefore, twelve of the fifteen species are always selected to be blended together in each batch. This type of labeling is not without precedence. Many prepared foods that use seasonal produce will indicate that the produce included in the package will vary seasonally.

3. It should be noted that one of the sea vegetable ingredients, Kombu Fucoidon, which is an extract of the brown seaweed *Kjellmaniella crassifloia*, has received FDA confirmation that "a dietary supplement containing Kombu Fucoidan is reasonably expected to be safe when used under the conditions recommended or suggested in the product's labeling."
4. The product label defines Serving Size as 1 capsule, and under Suggested Use: "As a dietary supplement for adults, up to three capsules per day." Higher dosages for those sick with chronic degenerative diseases is never stated or implied in the infomercial, or stated on the label, as Dr. Skibola contended.
5. Dr. Skibola has also questioned whether "the head of the Irish Seaweed Center is a scientific advisor" to the Company. In fact, Dr. Stefan Kraan, head of the Irish Seaweed Counsel and National Seaweed Research Coordinator, Marine Institute, Galway, Ireland, is on the company's science advisory board. Dr. Kraan's curriculum vitae is attached.
6. Dr. Skibola further states that the infomercial claims that "sick people can take even more without worry about OD'ing." This is never stated in the infomercial. What is stated in the infomercial is "The Japanese people, as a culture,eat an average of seven grams a day (of seaweed). That's over a bottle of this. So, don't worry about OD'ing."
7. Dr. Skibola also states that "it is my opinion that there is no scientific evidence that Sea Vegg™ can treat or prevent cancer, fibromyalgia, diabetes, arthritis, or multiple sclerosis". While the interviewer in the ITV infomercial asked Mr. Kennedy to address these issues, Mr. Kennedy was very careful to not make any claims that Sea Vegg™ would treat, cure, or prevent any of these degenerative diseases. Several times during the course of this discussion, the following required DSHEA disclaimer appeared on the screen "THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE." (For those who are visually impaired, a "voice-over" stated the disclaimer.)

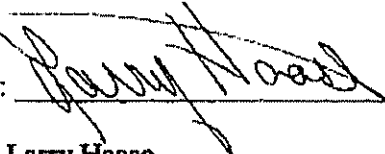
8. It is very interesting to note that although Dr. Skibola states that no scientific evidence exists that Sea Vegetation and or Sea Vegg™ can treat or prevent cancer, she has in fact published an article that contradicts her position. In her article titled "Brown Kelp Modulates Endocrine Hormones in Female Sprague-Dawley Rats and in Human Luteinized Granulosa Cells"¹, Dr. Skibola states "These data show endocrine modulating effects of kelp at relevant doses and suggest that dietary kelp may contribute to the lower incidence of hormone-dependent cancers among Japanese."
9. The only claim that we could directly attribute to Mr. Kennedy, or to the Company, was his contention that Sea Vegg™ "will normalize (people's) weight and begin to normalize their thyroid, which I believe is reasonably substantiated. People that are too underweight will gain weight and women that are overweight will begin to lose some pounds and inches right away without even trying." In her statement, Dr. Skibola says that there is no scientific evidence for weight normalization using Sea Vegg™. There is considerable scientific evidence that the iodine contained in seaweed (kelp) helps to normalize the thyroid which in turn normalizes weight for those subjects. In their article Pharmacological Treatment of Obesity, Drs Gerald Curzon and E. Leigh Gibson state: "Another herbal material that has long been used is the seaweed bladderwrack (*Fucus vesiculosus*), the iodine in which presumably increases thyroxine synthesis so that the metabolism of obese hypothyroidal subjects is accelerated. Bladderwrack preparations survive (as do other herbal remedies) in the list of drugs approved for the treatment of obesity by the UK Department of Health."
10. Dr. Skibola goes on at length about menstrual cycles in Japanese women and her research on same. This subject is never discussed on the infomercial, nor is there any claim on the package.
11. Finally, Dr. Skibola raises the question of safety of the product. Specifically, she raises the issue of the amount of heavy metals and arsenic. A Certificate of Analysis from the Company shows that the Sea Vegg™ meets the stringent standards established by the Company.

<u>TEST</u>	<u>SPECIFICATION</u>	<u>RESULT</u>
Arsenic	Not More Than 5 ppm	Conforms
Mercury	Not More than 0.5 ppm	Conforms
Lead	Not More than 10 ppm	Conforms

Additionally, the product conforms to the microbiological specifications established by the Company, including quantification of total plate count, yeast/mold, *Salmonella*, *E. coli*, and *Staphylococcus aureus*. (See Exhibit 1)

As a result of the above findings, I believe that Sea Vegg™ and ITV has complied with DSHEA and the FTC regulations concerning claims that have been stated about the viability of Sea Vegetation or Sea Vegg™ as a dietary supplement.

I hereby declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Signed:  Date: 06/08/05
Larry Haase